

REMARKS

Claims 1-20 and 24-30 are currently pending. Claims 21-23 were previously withdrawn without prejudice. Claims 28-30 have been added.

Claims 1-20 and 24-27 all stand rejected under 35 U.S.C. §102(b) based on U.S. Patent No. 4,611,582 to Duff. The claims have been amended to clarify the claimed subject matter.

The rejections, as they may apply to the claims presented herein, are respectfully traversed.

Claims 1-9 and 28-30 are directed to a connecting assembly for interconnecting spinal rods secured to spinal vertebrae having a pair of connecting devices at each end. The connecting devices have a locking member that shifts between clamped and unclamped positions, and a rotatable actuator that is rotatable by a predetermined rotary amount to a locked position and operable to shift the locking member into and out of the clamped position. The *Duff* reference does not disclose or suggest a locking member that shifts between clamped and unclamped positions by rotation of a rotatable actuator. Additionally, the *Duff* reference does not disclose or suggest a device having a rotatable actuator that is rotatable by a predetermined rotary amount to a locked position.

Duff discloses a vertebral clamp that controls the spatial relationship between two adjacent vertebrae by hooking portions of the vertebral bone. There is no suggestion or indication in *Duff* that such a clamp may be used as an assembly for interconnecting spinal rods, or that the profile of the *Duff* clamp would permit its use

as a connecting member for spinal rods. *Duff* further discloses a set screw located between a set of pivotable hooks. The set screw does not have a set locked position that may be arrived at by rotating the set screw by a predetermined amount.

The claimed rotatable actuator has a number of advantages over a set screw as shown by *Duff* and other prior art references. For instance, an actuator with a predetermined locked position provides a surgeon with certainty, since it is known that the device is locked when the actuator is rotated by a predetermined amount. By contrast, it is not clear when a set screw as in *Duff* is fully engaged with its target, leaving the surgeon to determine whether or not the set screw “feels” secured. This may result in a failure to lock the device or accidental over-torquing. The rotatable actuator with a set locked position also avoids the potential for cross-threading, another problem also associated with set screws. Therefore, the rotatable actuator minimizes unwanted stress and physical damage to the rod, connecting device, and the actuator itself.

Claims 4-6 are also further patentable over *Duff*, since *Duff* further lacks a “spring retention member for biasing the locking member in the unclamped position.” The lock washer (53) of *Duff* does not satisfy this limitation, since it does not bias a locking member in the unclamped position as required by the claims. Rather, the lock washer of *Duff* simply retains the ball of the clamp in its corresponding socket.

Claims 10-20 are directed to a connecting assembly having two spinal rod connecting devices, one connecting device attached to a cross rod and the other connecting device attached to a receiving member with a bore that receives the free end of the cross rod. The cross rod may be pivoted or shifted axially within the

receiving member so that the depth and angle of the cross rod with respect to the receiving member may be adjusted. A sleeve and clamp device are also provided, so that the sleeve clamps the clamp device against the cross rod to fix the cross rod at an adjusted angle and adjusted depth within the receiving member. *Duff* does not disclose or suggest an assembly with a cross rod that may be pivoted within a bore to provide variable angles. *Duff* also does not disclose or suggest a sleeve that clamps a clamp device against a cross rod to fix the cross rod at an adjusted angle and adjusted depth within a receiving member.

Duff shows an assembly that permits axial extension of a longitudinally extending body by rotating members of the body relative to each other. In *Duff*, rotation of a threaded cap (37) relative to a threaded nut member (34) adjusts the length of the body as threaded surfaces cause an axial shift of components. Although these threads prevent unwanted axial extension, they do not generate any radial clamping forces against the cross rod that would allow the cross rod to be locked at an adjusted angle. (See *Duff*, Fig. 5 and col. 3 ln 46 to col. 4 ln 25). *Duff* also does not disclose a rod receiving member having a bore with structure that would permit a cross rod to be pivoted with respect to the receiver member, and therefore for this further reason cannot function to clamp the cross rod at an adjusted angle and an adjusted depth within the receiving member as required by claims 10-20.

Claims 24-27 are directed to a connecting assembly having a pair of connecting devices, with a cross rod attached to one connecting device and a receiving member connected to the other connecting device. The receiving member has an internal bore that receives the free end of the cross rod. A sleeve and clamp device

secure the position of the cross rod relative to the receiving member, with the sleeve clamping the clamp device against the cross rod. The receiving member further contains side openings that open to the bore and allow the end of the cross rod to pivot in and out of the side openings. The claimed side openings are advantageous in that they allow the diameter of the receiver member to be minimized while still permitting the cross rod to pivot within the receiver member. Without side openings, a large cavity must be provided within the receiver member so that the cross-rod does not abut the interior surface of the receiver when pivoting.

The *Duff* clamp does not permit pivotal movement of the cross rod relative to the receiving member, and does not have a sleeve or clamp device to clamp against the cross rod, as explained above. Claims 24-27 are therefore patentable over *Duff* for those reasons alone. Furthermore, *Duff* does not have side openings into which a cross rod can pivot. The manipulating holes (62) of *Duff* are not equivalent to the claimed side openings, and are meant only to externally receive a tool for turning the nut member, not to allow the cross rod additional room to pivot. (See *Duff* at col. 6 lns 1-5). A rod cannot pivot into and out of the receiver holes of *Duff*.

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CONCLUSION

For the foregoing reasons, it is respectfully requested that claims 1-20 and 24-30 be allowed to pass to issue.

The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication or credit any overpayment to Deposit Account No. 06-1135.

Respectfully submitted,
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